Medicaid Briefing Papers

Governor's Pharmacy Reimbursement Commission
November 17, 2005

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Wisconsin Medicaid Pharmacy Reimbursement

The 2005-07 state budget requires modification of the current Medicaid and BadgerCare fee-for-service (FFS) drug reimbursement policy by increasing the discount rate for brand drugs from AWP -13% to AWP –16%. The proposal also decreases the dispensing fee by 50 cents from $4.38 to $3.88. The table below reflects the estimated savings, based on an effective date of September 1, 2005.

SeniorCare drug reimbursement rates are authorized under Wis. Stats., s.49.688 (1) (e). Prescription drug reimbursements are equal to payment rates established for identical drugs in Medicaid fee-for-service, plus a 5% supplement (AWP only). As such, the budget decreases SeniorCare drug reimbursement and dispensing fees.

Medicaid, BadgerCare and SeniorCare
Average Wholesale Price and Pharmacy Dispensing Fees
2005-07 State Budget Fiscal Effect

SFY 2006	**GPR**	**FED**	**All Funds**
AWP Change	$ (3,921,300)	$ (4,941,300)	$ (8,862,600)
Dispensing Fee	$ (1,275,360)	$ (1,626,821)	$ (2,902,181)
Total	$ (5,196,660)	$ (6,568,121)	$ (11,764,781)

SFY 2007	**GPR**	**FED**	**All Funds**
AWP Change	$ (6,020,000)	$ (7,334,500)	$ (13,354,500)
Dispensing Fee	$ (1,746,514)	$ (2,316,540)	$ (4,063,054)
Total	$ (7,766,514)	$ (9,651,040)	$ (17,417,554)

SFY 2006 and 2007	**GPR**	**FED**	**All Funds**
Total AWP	$ (9,941,300)	$ (12,275,800)	$ (22,217,100)
Total Dispensing Fee	$ (3,021,874)	$ (3,943,361)	$ (6,965,235)
Total Biennium	$ (12,963,174)	$ (16,219,161)	$ (29,182,335)

Medicaid Outpatient Pharmacy Payment Policy

The Department of Health and Family Services (DHFS) determines maximum reimbursement rates for all covered over-the-counter (OTC) and legend pharmaceutical items. Maximum reimbursement rates may be adjusted to reflect market rates, reimbursement limits, or limits on the availability of federal funding as specified in federal law (42 CFR 447.331).

All covered legend and OTC drugs are reimbursed at the lower of the estimated acquisition cost (EAC) plus a dispensing fee or the provider's usual and customary charge. EAC is determined based on the DHFS' best estimate of prices currently and generally paid for pharmaceuticals, using marketplace research or discounted published average wholesale prices.

- Average Wholesale Price (AWP) – The average list price that a manufacturer suggests wholesalers charge pharmacies. AWP is typically less than the retail price, which will include the pharmacy's own markup.
  - Wisconsin Medicaid currently discounts 13% from AWP.
  - The Governor's budget for the SFY 2005-2007 biennium proposed to reduce reimbursement to pharmacies to AWP-16%.
- Legend drugs for which there is not a generic equivalent or the brand is medically necessary are reimbursed at AWP - 13% plus a dispensing fee or the provider's usual and customary charge (U&C), whichever is less.
- Legend drugs for which there is a generic equivalent and the brand has not been indicated medically necessary, are reimbursed at the drug's price on the Medicaid Maximum Allowed Cost (MAC) List plus a dispensing fee or the U&C, whichever is less.
- For the SeniorCare program, pharmacies are paid a 5% enhancement to the Medicaid ingredient cost plus a dispensing fee or the U&C, whichever is less.

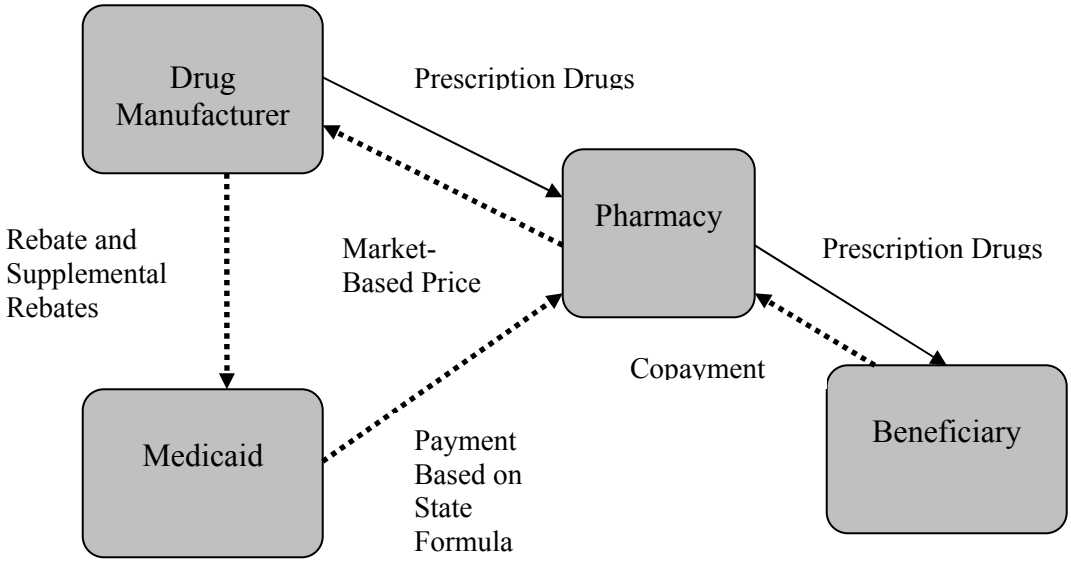
Dispensing fees

- Traditional dispensing fee – $4.38 per prescription, typically paid once per recipient, per service, per month, per provider. The Governor's budget proposed reducing it to $3.88.
- Repackaging allowance – $0.015 per unit repackaged; in addition to the traditional dispensing fee or pharmaceutical care dispensing fee.
- Compound drug dispensing fee – Reimbursed for the pharmacist's compounding time, which is indicated by the level of service.
- Pharmaceutical Care (PC) dispensing fee – An enhanced dispensing fee for providing additional services to a Medicaid recipient that results in a positive outcome for both the recipient and for Wisconsin Medicaid.

Medicaid Program Pharmacy Expenditures: State Fiscal Year 2004-05

- Medicaid & BadgerCare Paid Amount (All Funds): $654.6 million
- Medicaid & BadgerCare Paid Claims: 10.8 million
- SeniorCare Paid Amount (All Funds): $130.2 million
- SeniorCare Paid Claims: 3.5 million

Medicaid's System for Purchasing Prescription Drugs



- A Medicaid beneficiary obtains a prescription drug from a participating pharmacy, which has previously purchased the drug in the marketplace from a manufacturer or wholesaler.

- The pharmacist receives payment from Wisconsin Medicaid based on the estimated acquisition cost of the drug, which is either AWP-13% or the MAC price plus a dispensing fee or the pharmacy's usual and customary charge, if it is less than the State's approximation of acquisition cost.

- The manufacturer pays rebates directly to Wisconsin Medicaid, which also receives matching payment from the federal government. For the SeniorCare program, federal matching payments are made only to the State for expenditures made on behalf of waiver participants (at or below 200% FPL). Manufacturer rebates are shared with the federal government based on the share of matching funds it pays the state, e.g., if the federal government pays sixty cents of every dollar expended, it receives sixty cents of every dollar received as rebate revenue.

Wisconsin Medicaid Drug Pricing:
Average Wholesale Price and Maximum Allowable Cost

- Background
  - Medicaid does not buy drugs – Medicaid pays pharmacies.
  - There are over 100,000 National Drug Codes (NDCs) on the Medicaid drug file and processed online in real time; therefore pricing must be done through drug databases.
  - Drug databases rely on standard industry price sources, e.g. First Data Bank (Blue Book), Medispan (Red Book).

- EAC is defined as the Medicaid agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. Wisconsin Medicaid determines the estimated acquisition cost (EAC) for most drugs through two methods.

- Wisconsin's methods for determining EAC are:
  - Maximum Allowed Cost (MAC) is used when the drug is a generic drug that is readily available from multiple companies.
  - Average Wholesale Price (AWP) minus 13% is used for most brand products (drugs still on patent) and generic drugs not on the MAC list.
    - AWP represents the package price reported by the manufacturer or based on surveys of drug wholesalers and drug manufacturer-supplied information for a drug product. Actual AWP is determined by individual wholesalers and may vary.

  For most drugs Wisconsin Medicaid bases drug cost on Average Wholesale Price (AWP). Every two weeks Medicaid's open formulary system automatically updates the cost of drugs, based on AWP as reported by manufacturers to First Data Bank.

- Approximately 7 Medicaid programs use WAC prices (e.g., WAC +10%) to establish brand drug payment rates. WAC Price is commonly referred to as "List Price," "Wholesale Acquisition Cost," "Invoice Price," or "Direct Price."
  - WAC represents the price per package of a drug product that a manufacturer charges a wholesaler.
    - WAC methodology is conceptually similar to generic MAC pricing methodology (see below).
    - States may believe WAC prices insulate Medicaid from rapid manufacturer price increases.

- Both AWP and WAC prices are subject to routine manufacturer price increases and neither AWP nor WAC prices are independently verified reflecting actual and accurate prices.

- Average Sales Price (ASP)
  - The ASP for a drug is the total revenue received by the manufacturer for the drug divided by the total number of units sold. All sales are included in the calculation, except sales at nominal prices and sales to the government, Public Health Service grantees, and certain other entities.

For Medicare Part B covered drugs, manufacturers will report ASP information to CMS for each quarter, and CMS will revise the payment amounts each quarter based on the most recent available ASP data. If a manufacturer is uncertain about the revenue for a particular quarter because of rebates and chargebacks for which final information in not yet available, the manufacturer is to use a 12-month rolling average to estimate what the final revenue will be for a drug.

The payment rate for a single source drugs will be 106% of the wholesale acquisition cost (WAC) if that is lower than 106% of ASP. Since WAC is the list price of a drug, that situation is unlikely to occur.

- Wisconsin Medicaid has adopted the Medicare ASP rate for physician-administered drugs.

The Office of Inspector General (OIG) is required to compare the ASP for drugs to the drug's "widely available market price" (WAMP) and its "average manufacturer price" (AMP), which is the average price at which the manufacturer sells a drug to wholesalers for the retail pharmacy class of trade. ASP includes discounts given to large volume purchasers such as hospitals and HMOs, whereas WAMP and AMP do not.

- Maximum Allowable Cost (MAC) Program

The Wisconsin Medicaid Maximum Allowable Cost (MAC) Program establishes maximum allowable reimbursement for generic drugs available from with multiple manufacturers/sources. The MAC program mandates generic drug use unless the prescribing physician indicates that use of a brand name drug is required under certain criteria.

Under the MAC program, which mandates generic drug use, 99% of drugs available from multiple sources are dispensed generically. Prescribers can mandate the brand by indicating in their own handwriting "brand medically necessary;" however, most brand name drug use is for drugs with narrow therapeutic indices such as cardiac or seizure medications.

The Wisconsin Medicaid MAC pricing is based on principles promoted by the federal government in order to limit drug ingredient payments to actual costs. The Wisconsin MAC policy allows for price adjustments based in part on provider's documented invoice/cost information. Wisconsin MAC prices are considered a model, used by other public and private payers as a basis for establishing generic drug prices. A comparison of Wisconsin and national averages follows.

- Average prescription cost in 2004
  - Generic drugs
    - Wisconsin Medicaid $18.12
    - National Average $28.74 (Source: NACDS)
  - Brand drugs
    - Wisconsin Medicaid $120.12
    - National Average $96.01 (Source: NACDS)

- Average generic prescription utilization in 3rd quarter 2005
    - Wisconsin Medicaid 62%
    - National Average 55% (Source: Express Scripts)

The Wisconsin MAC list:

- Includes over 1,000 drugs.
- Applies to most generic legend and all over the counter (OTC) drugs.
- Requires a generic drug to be readily available, but not necessarily from 3 sources.
- In theory, uses prices pharmacists actually pay for drugs.

- MAC Drug Selection

The following criteria are applied in selecting a drug for establishment of a Wisconsin MAC price:

- Drugs must have two or more sources that are uniformly available to Wisconsin pharmacies.
- MAC prices must be at least 25% less than innovator prices.
- Drugs on the LIST must be "A" (e.g., AA, AB) rated in the FDA Orange Book.
- MAC prices are established for all covered OTC and most generic legend drugs.

- Establishing MAC Prices

The process for establishing and reviewing MAC prices on a quarterly basis includes:

- DHCF determines actual wholesale prices to pharmacies from drug wholesalers and buying groups.
- Prices are set at approximately 10-25% more than the lowest acquisition price.
- New MAC lists are published quarterly.

Wisconsin Medicaid Drug Rebates

Federal law {42 U.S.C. § 1396r-8(d) (1)(A)} requires that manufacturers who wish their drugs to be eligible for coverage by Medicaid must first sign a rebate agreement with CMS. This rebate agreement requires that manufacturers:

- Submit their Average Manufacturer Price (AMP) and their Best Price (BP) to CMS within 30 days of the end of each quarter. The AMP and BP are used to calculate the rebate amount.
- Reimburse states the larger of 15.1 percent of AMP per unit or the difference between AMP and best price per unit, adjusted by the CPI-U based on market date and current quarter AMP for innovator drugs.
- Reimburse states 11 percent of AMP per unit without a CPI-U adjustment for non-innovator drugs.

States must submit utilization data on a quarterly basis to each manufacturer (and CMS). The data must identify, by National Drug Code (NDC) number, the number of units paid for by the state for each covered outpatient drug.

Rebate Process

- CMS sends states a quarterly tape containing the rebate amount owed per unit for each covered NDC.

- States create and send invoices to manufacturers on a quarterly basis for the number of units of product reimbursed in the previous quarter.

- Manufacturers have 30 days from the receipt of a state invoice to pay the rebate. Interest on unpaid or disputed rebates begins accruing 38 calendar days after the State sends an invoice to a manufacturer.

- If the manufacturer disagrees with the units invoiced and the amount of the rebate which cannot be resolved by the due date, the dispute resolution process should be initiated.

Rebate Collections

The federal rebate process has resulted in significant revenue for Medicaid from drug manufacturers. Below are the All Funds amounts received in drug rebate for the last three state fiscal years (SFY).

SFY 03	$106,734,194 (21% of drug expenditures)
SFY 04	$133,862,344 (25% of drug expenditures)
SFY 05	$169,057,198 (28% of drug expenditures)

Federal Proposals to Change Medicaid Pharmacy Reimbursement

The President's 2006 budget included a shift in the Medicaid reimbursement formula from AWP to average sales prices (ASPs) – generating an estimated savings of $5.4 billion over five years.

Subsequently, the Bush administration's Medicaid Commission endorsed an alternative pharmacy reimbursement formula that is also endorsed by the National Governor's Association. The Commission proposal would base Medicaid pharmacy reimbursement on the Average Manufacturers' Price (AMP) and provide for reforms to modify and ensure the accuracy of manufacturer pricing information. Compared to the President's ASP proposal, the use of AMP is estimated to reduce savings to the federal government by approximately $4.3 billion over five years. In general, ASP differs from AMP in that it includes discounted prices given to PBMs, insurers and hospitals, which pharmacies do not receive.

Congress

Both the House and Senate budget proposals include reform relating to Medicaid drugs and pharmacy. Both versions seek to reduce overall Medicaid spending by approximately $10 billion over five years. Currently, the proposals include the following provisions.

Senate

Medicaid Prescription Drug Payment Reforms:

1. Redefines average manufacturer price (AMP) to reflect discounts and rebates available to retail pharmacies and then uses that definition for payments to pharmacies and for the calculation of the best price.
2. Defines weighted average manufacturer price (WAMP) as the basis of a new payment system for these drugs and for a new federal upper limit for multiple source drugs.
3. Clarifies nominal price definition to ensure that sales made at a nominal price are appropriately included in AMP calculations.
4. Creates a new federal upper limit for payments to states for covered drugs that goes into effect January 1, 2007 (with a later transition for states without 2006 legislative sessions) of AMP+5% for single source drugs and WAMP+15% for multi-source drugs.
5. Includes language that requires states to provide appropriate dispensing fees to pharmacists and sets factors upon which they should be based.
6. Creates an interim payment policy for 2006 capping the current federal upper limit at 125% of the July 1, 2005 AWP, WAC, or direct price levels.

Prescription Drug Rebates and Related Programs

7. Improved regulation of authorized generic drugs. This section requires CMS to include the best price of an authorized generic in the calculation of the best price for the branded drug.
8. Increase in rebates for covered outpatient drugs. This section increases the rebate paid by innovator drug manufacturers from 15.1% to 17% and on noninnovator drugs from 11% to 17%

House

Medicaid Prescription Drug Payment Reforms:

1. Eliminates use of the average wholesale price (AWP) formula, which often results in large markups of prescription drugs.
2. Institutes use of retail average manufacturer price (RAMP) to calculate drug reimbursement costs, which are more in line with actual costs.
3. Revises federal law to set an upper limit for Medicaid prescription drug reimbursement for all outpatient covered drugs. The limit would be 106 percent for single-source drugs and 120 percent for generic drugs.
4. Pharmacist fees for generic drugs will be raised to $8, twice the national average, which will encourage more generic drug prescriptions.
5. Creates a $100 million fund to encourage states use more generic drugs and implement medication risk management programs.

Flexibility in State Medicaid Program Design

6. States would have the option of using the health coverage plan offered to state employees, the largest state private Health Maintenance Organization plan, or the Federal Employee Health Benefit Plan as benchmarks for state Medicaid coverage.
7. Allows states to nominally increase cost sharing over a three-year period. Co-payments of $3 today could rise to $5 by 2008. States would have the authority to make co-payments and other cost sharing enforceable.
8. Allows states to charge tiered co-payments in order to encourage beneficiaries to use prescription drugs identified by the state as least costly effective prescription drugs within a class of drugs. [An amendment approved that exempts mental health drugs from this provision]

Preferred Drug List and Supplemental Rebate Program

In October 2004, Wisconsin Medicaid began phasing-in a Preferred Drug List (PDL) and Supplemental Rebate Program. To date, 48 drug categories have been reviewed.

The main objectives of this project are to:

- Reduce Wisconsin Medicaid drug costs through effective PDL management and negotiation of supplemental rebates.
- Maintain client access and existing program operations by integrating the PDL with current Medicaid PA functions.
- Increase the cost effectiveness of drug utilization by providing clinical expertise on recommended products.
- Implement the PDL in a manner that causes the least amount of disruption to the program's providers, prescribers and clients.
- Create incentives and opportunities for pharmaceutical manufacturers to provide comparable pricing to preferred drug products through the supplemental rebate mechanism.

The PDL has been designed and maintained to promote the use of generic and lower cost brand products that are considered to be clinically comparable and as medically effective as higher cost options in the same drug class. The PDL has been designed to achieve market shift toward generic and lower cost brand products. It employs the following processes and meets the following criteria:

- A stringent clinical review of medical and scientific data to evaluate drug classes and determine which products provide equivalent clinical outcomes. The review includes careful consideration of the impact of establishing preferred products on the health and safety of the Wisconsin Medicaid population.
- Recommendations are made for preferred drugs based on a thorough review of clinical effectiveness, safety and health outcomes, followed by an analysis of relative costs of the alternative drugs in each class under consideration. Drugs shown to provide similar effectiveness, which are less costly, will be identified as preferred drugs.
- The Wisconsin Medicaid Program and PA Advisory Committee review all recommendations, with final approval provided by the DHFS Secretary.
- PDL requirements are implemented as much as possible within the framework of Wisconsin Medicaid's existing STAT PA program.

Negotiating and establishing supplemental rebate agreements is the second primary requirement for this project. This requirement provides manufacturers the opportunity to offer supplemental rebates to bring the State's cost for their products to a level comparable to the preferred drugs, thus avoiding a PA requirement. Through June 30, 2005, it is estimated that Wisconsin Medicaid has achieved $16.7 million All Funds savings from supplemental rebates.

In August 2005, Wisconsin joined Maryland, West Virginia and Louisiana in a multi-state PDL known as TOP$. Participation in TOP$ is expected to increase supplemental rebate savings even further.

Wisconsin Specialized Transmission Approval Technology--Prior Authorization

Wisconsin Medicaid allows pharmacy providers to submit prior authorization (PA) requests through the Wisconsin Specialized Transmission Approval Technology--Prior Authorization (STAT-PA) system for Wisconsin Medicaid and BadgerCare fee-for-service recipients and SeniorCare participants. The STAT-PA system allows Medicaid-certified pharmacy providers to request and receive PA electronically, rather than on paper, for most drugs.

All 48 of the Preferred Drug List (PDL) classes as well as Selective Serotonin Reuptake Inhibitor drugs, Alpha-1 Proteinase Inhibitors and Anti-Obesity Drugs are available on the STAT-PA system. Currently, there are six class specific PDL exemption request forms as well as a generalized PDL form and a form for each of the additional classes available on STAT-PA.

Prescriber Responsibilities

Prescribers are required to complete and sign the exemption request forms and send the form to the pharmacy where the prescription will be filled. Prescribers must retain this form and all clinical documentation supporting the use of the requested drug in the recipient's medical record. Prescribers are responsible for providing clinical information to the pharmacy for the PA requests.

Pharmacy Provider Responsibilities

Pharmacy providers must have a completed and signed exemption form from the prescriber in order to request PA using the STAT-PA system. Pharmacies are required to retain a copy of the exemption request forms.

Pharmacies must enter their Medicaid provider number, the recipient's MA number, the NDC of the drug requested, the diagnosis code, as well as other information to begin using the STAT-PA system. The STAT-PA system, based on the NDC entered, will ask a series of clinically based questions for each class to determine if the PA should be approved.

Pharmacy providers can access the STAT-PA system using their touchtone telephones from 8:00 a.m. to 11:45 p.m., seven days a week. The STAT-PA Help Desk is also available 8:00 a.m. to 6:00 p.m., Monday through Friday. Pharmacies may request 25 PAs per telephone call.

WISCONSIN MEDICAID

PRIOR AUTHORIZATION / PREFERRED DRUG LIST (PA/PDL) EXEMPTION REQUEST

INSTRUCTIONS: Type or print clearly. Before completing this form, read the Prior Authorization/Preferred Drug List Exemption (PA/PDL) Completion Instructions (HCF XXXXXA).

Dispensing providers must have a completed PA/PDL Exemption Request Form signed by the prescriber before calling STAT-PA or submitting a paper PA request.

SECTION I — RECIPIENT INFORMATION

1. Name — Recipient (Last, First, Middle Initial)	2. Date of Birth — Recipient
3. Recipient Medicaid Identification Number	

SECTION II — PRESCRIPTION INFORMATION

4. Drug Name	5. Strength
6. Date Prescription Written	7. Directions for Use
8. ICD-9-CM Diagnosis Code and/or Description	
9. Name — Prescriber	10. Drug Enforcement Agency Number
11. Address — Prescriber (City, State, Zip Code)	
12. Telephone Number — Prescriber	

SECTION III — CLINICAL INFORMATION

13. Has the patient experienced treatment failure with the preferred product(s)? ❑ Yes ❑ No
If Yes, list the preferred drugs that failed and the dates taken below:

14. Does the patient have condition(s) preventing the use of the preferred product(s)? ❑ Yes ❑ No
If Yes, list the conditions below:

15. Is there a clinically significant drug interaction between another medication the patient is taking and the preferred product(s)? ❑ Yes ❑ No
If Yes, list the medications and interaction(s) below:

16. Has the patient experienced intolerable side effects while on the preferred product(s)? ❑ Yes ❑ No
If Yes, list the side effects below:

17. **SIGNATURE** — Prescriber	18. Date Signed

Continued

SECTION IV — FOR PHARMACY USE ONLY

19. National Drug Code (NDC) (11 digits)	20. Days Supply Requested*

21. Wisconsin Medicaid Provider Identification Number (8 digits)

22. Date of Service (MM/DD/YYYY) (For STAT-PA requests, the date of service may be up to 31 days in the future and or up to 14 days in the past.)

23. Place of Service (Patient Location) Use patient location code 00 (Not specified), 01 (Home), 04 (Long Term/Extended Care), 07 (Skilled Care Facility), or 10 (Outpatient)

24. Assigned Prior Authorization Number (7 digits)

25. Grant Date	26. Expiration Date	27. Number of Days Approved

*Days supply requested equals the total number of days requested for the PA. For example, for a one-year PA, providers should enter "365."

SECTION V — ADDITIONAL INFORMATION

28. Include any additional information in the space below. For example, providers may include that this PA request is being submitted for a recipient who was granted retroactive eligibility by Wisconsin Medicaid, BadgerCare or SeniorCare.

Brand Medically Necessary Prior Authorization

Wisconsin Medicaid implemented a revised Brand Medically Necessary (BMN) Prior Authorization (PA) policy in September 2004. The policy requires PA for prescriptions for brand name drugs where there is a generic available on the Medicaid Maximum Allowable Cost (MAC) list. The drugs excluded from the policy are the generic Selective Serotonin Reuptake Inhibitor drugs, citalopram, fluoxetine, and paroxetine as well as the narrow therapeutic index drugs, Clozaril, Coumadin, Dilantin, Neoral and Tegretol.

Generic drugs on the MAC list must be "A" (e.g., AA, AB) rated as listed in the Food and Drug Administration (FDA) Orange Book. Currently, Wisconsin Medicaid requires brand medically necessary PA for over 400 drugs. Since the MAC list can be updated monthly, the number of drugs requiring PA may also be updated each month.

Prior Authorization Requirements

To request PA, prescribers must complete and sign the Prior Authorization/Brand Medically Necessary Attachment (PA/BMNA), see attached, and submit it to the pharmacy where the prescription will be filled. The attachment requires the prescriber to indicate the reason for ordering a brand name drug and provide the criteria necessary to approve a PA request. Approval criteria include:

- a therapeutic failure of the generic drug(s).
- an adverse reaction to the generic drugs(s).
- an allergic reaction to the generic drug(s).

Prescribers are required to indicate "Brand Medically Necessary" on the prescription order. Once the pharmacy receives the PA/BMNA and the prescription order, the pharmacy completes and signs the Prior Authorization Request Form (PA/RF) and sends the PA/RF, the prescription order and the PA/BMNA to the Medicaid fiscal agent for review.

Narrow Therapeutic Index Drugs

The FDA identifies a drug that has a narrow therapeutic index (NTI) if very small changes in the dosage level could cause toxic results. These drugs require constant patient monitoring so that the level of medication can be adjusted as necessary to assure uniform and safe results. In April 2005, to accommodate BMN PA requests for NTI drugs, including Clozaril, Coumadin, Dilantin, Neoral and Tegretol, Wisconsin Medicaid added an additional PA approval criterion:

- An anticipated therapeutic failure of the generic drug(s).

DEPARTMENT OF HEALTH AND FAMILY SERVICES **STATE OF WISCONSIN**
Division of Health Care Financing
HCF 11083 (03/05)

WISCONSIN MEDICAID
PRIOR AUTHORIZATION / BRAND MEDICALLY NECESSARY ATTACHMENT (PA/BMNA)

INSTRUCTIONS: Type or print clearly. Before completing this form, read the Prior Authorization/Brand Medically Necessary Attachment (PA/BMNA) Completion Instructions (HCF 11083A).

Prescribers are required to submit this completed form to the dispensing provider where the prescription will be filled.

Dispensing providers may submit prior authorization (PA) requests by fax to Wisconsin Medicaid at (608) 221-8616 or by mail to Wisconsin Medicaid, Prior Authorization, Suite 88, 6406 Bridge Road, Madison, WI 53784-0088.

SECTION I — RECIPIENT INFORMATION

1. Name — Recipient (Last, First, Middle Initial)	2. Date of Birth — Recipient
3. Recipient Medicaid Identification Number	

SECTION II — PRESCRIPTION INFORMATION

4. Drug Name	5. Strength(s)
6. National Drug Code (NDC)	7. Date Prescription Written
8. Directions for Use	9. Start Date Requested
10. Diagnosis — Primary Code and / or Description	
11. Name — Prescriber	12. Drug Enforcement Agency Number
13. Address — Prescriber (Street, City, State, Zip Code)	
14. Telephone Number — Prescriber	

15. Is "Brand Medically Necessary" handwritten by the prescriber on the prescription? ❑ Yes ❑ No

SECTION III — CLINICAL INFORMATION

16. Has the recipient experienced an adverse reaction to the generic drug? ❑ Yes ❑ No
If yes, indicate the adverse reaction that can be directly attributed to the generic drug in the space provided.

17. Has the recipient experienced an allergic reaction to the generic drug? ❑ Yes ❑ No
If yes, indicate the allergic reaction in the space provided.

18. Has the recipient experienced an actual therapeutic failure of the generic drug? ❑ Yes ❑ No
If yes, indicate the actual therapeutic failure in the space provided.

19. For the following drugs only: Clozaril, Coumadin, Dilantin, Neoral, or Tegretol
Is there an anticipated therapeutic failure of the generic drug? ❑ Yes ❑ No
If yes, indicate the anticipated failure in the space provided.

20. SIGNATURE — Prescriber	21. Date Signed

SECTION IV — ADDITIONAL INFORMATION

22. Include any additional information in the space below. For example, providers may include that this PA request is being submitted for a recipient who was granted retroactive eligibility by Wisconsin Medicaid, BadgerCare, or SeniorCare.

Pharmaceutical Care

Since 1996, Wisconsin Medicaid has provided an incentive-based pharmacy payment system that pays for Pharmaceutical Care (PC) services. Pharmaceutical Care is a nationwide movement promoting a patient-centered, outcomes-oriented practice of pharmacy. Its purpose is to maximize the effectiveness of medications for patients through intervention by the pharmacist. The enhanced dispensing fee is also designed to ensure budget neutrality.

The Wisconsin Medicaid PC program provides pharmacists an enhanced dispensing fee for services given to Wisconsin Medicaid and BadgerCare fee-for-service recipients and SeniorCare participants. The enhanced fee reimburses pharmacists for additional actions taken beyond the standard dispensing and counseling for a prescription drug.

Pharmaceutical Care Profile—Pharmacy Requirements

A PC profile must be created and maintained for each recipient prior to submitting a PC claim. It must include the diagnosis (ICD-9-CM) for each drug the recipient is using. The source of information and level of confidence must be documented. Each PC profile must contain sufficient clinical information about the recipient to make relevant clinical decisions and recommendations.

Pharmaceutical Care Dispensing Fee

Reimbursement for the PC dispensing fee requires the pharmacist to meet all basic requirements of federal and state law for dispensing a drug plus completing specified activities that result in a positive outcome both for the recipient and the Wisconsin Medicaid program. For example, positive outcomes may include increasing patient compliance or preventing potential adverse drug reactions. Reimbursement is based on the following:

- The *reason* for intervention.
- The *action* taken by the pharmacist.
- The *result* of that action.
- The time spent performing the intervention.

Providers may submit claims for PC services as real-time claims or on the non-compound drug claim form using PC codes in the three fields shared with drug utilization review (DUR). Providers should determine the total billed amount by adding the usual and customary fee for the drug charge and the usual and customary fee for the PC service.

State Fiscal Year 2004-05 Pharmaceutical Care Claims and Expenditures

Wisconsin Medicaid reimbursed 201 pharmacy providers a total of $164,535 for 6,989 pharmaceutical care claims.

Medicaid Prospective Drug Utilization Review

The federal Omnibus Budget Reconciliation Act of 1990 (OBRA `90) established Medicaid program requirements regarding several aspects of pharmacy practice including a Drug Utilization Review (DUR) program for Medicaid outpatients to improve the quality and cost-effectiveness of recipient care performed independently by pharmacists.

To help individual pharmacies comply with their prospective DUR responsibility, Wisconsin Medicaid developed a prospective DUR system, based on the recommendations of the Wisconsin Medicaid DUR Board. Prospective DUR screens certain drug categories for clinically significant potential drug therapy problems before the prescription is dispensed to the recipient. Prospective DUR enhances clinical quality and cost-effective drug use.

Prospective DUR Alert Hierarchy

Wisconsin Medicaid administers alerts that identify the following problems, presented in hierarchical order:

- Drug-drug Interaction (DUR conflict code DD).
- Drug-disease contraindication (reported [MC] and inferred [DC]).
- Therapeutic duplication (TD).
- Pregnancy Alert (PG).
- Early Refill (ER).
- Additive Toxicity (AT).
- Drug-age precaution (pediatric [PA]).
- Late refill (LR).

The Wisconsin Medicaid DUR Board has established the hierarchy prioritizing the potential for avoidance of adverse consequences, improvement of the quality of care, and cost savings.

Prospective DUR Alerts

When a claim is submitted through the Point-of-Sale system for a drug that has the potential to cause problems for the recipient, an alert is returned to inform the pharmacy of the potential problem. The provider is then required to resubmit the claim and override the alert in order to obtain reimbursement from Wisconsin Medicaid. The override must include information about the action taken and the resulting outcome. The system also allows pharmacy providers to pre-override alerts if the drug in claims history that activates the alert was dispensed from the same pharmacy. Real-time claims for nursing home recipients are reviewed through the prospective DUR system; however, alerts set for these recipients are informational only and do not require a response to obtain reimbursement.

Retrospective Drug Utilization Review

The federal Omnibus Budget Reconciliation Act of 1990 (OBRA `90) established Medicaid program requirements regarding several aspects of pharmacy practice. One of the requirements of OBRA `90 was a Drug Utilization Review (DUR) program for Medicaid outpatients to improve the quality and cost-effectiveness of recipient care.

Providers should refer to Phar. 7.01(1)(e) and 7.08, Wis. Admin. Code, and 450.01(16)(i), Wis. Stats., for detailed information about Wisconsin's DUR requirements.

The OBRA `90 requires that Medicaid DUR programs should have all the following:

- Prospective DUR
- Retrospective DUR
- An education program using DUR program data on common drug therapy

Individual pharmacies are responsible for prospective DUR, while Wisconsin Medicaid is responsible for the retrospective DUR and the educational program.

Retrospective Drug Utilization Review Activities

Retrospective DUR reviews are performed by Wisconsin Medicaid on a monthly basis. Review of drug claims against DUR Board-approved criteria generates patient profiles that are individually reviewed for clinical significance. The attached table shows the Wisconsin Medicaid Retrospective DUR criteria by therapeutic category and drug problem type.

Each month, all Medicaid fee-for-service pharmacy claims are examined by a software program for potential adverse drug concerns. Among the problems reviewed are drug/drug interactions, overuse (early refill), drug/disease contraindication, duplicate therapy, high dose, and drug pregnancy contraindication.

If a potential drug problem is discovered, intervention letters are sent to all providers who ordered a drug relevant to the identified problem. Criteria are developed by Wisconsin Medicaid and are reviewed and approved by the DUR Board. An intervention consists of an informational letter to the prescriber, a response form for the prescriber to complete, a pre-addressed return envelope, and a patient drug profile.

Between October 2002 and September 2004, Wisconsin Medicaid conducted an average of 832 retrospective DUR reviews per month and sent an average of 263 intervention letters per month.

Wisconsin Medicaid has conducted various analyses to determine the cost savings associated with retrospective DUR. For state fiscal years (SFYs) 2003 and 2004, an analysis of drug costs associated with a recipient before and after a DUR letter intervention was sent showed savings of $99,816. A subsequent analysis used a model that incorporated all costs associated with a patient. Using this model, the cost savings for all services in SFY 2003 was $219,744.

RETROSPECTIVE DUR CRITERIA

DRUG PROBLEM TYPE											
Therapeutic Category	ID	IDU	OU	UU	DDI	DDC	TD	HD	O^1	O^2	O^3
Acetaminophen								X			
Antipsychotics					X	X				X	
NSAIDS					X	X	X			X	
H_2 Antagonists			X		X	X	X				
Hypnotics			X				X				
Antidepressants (TCAs)					X		X		X	X	
Antidepressants (SSRIs)					X		X			X	
Anticoagulants					X						
Anxiolytics/Sedatives			X		X	X	X			X	
ACE Inhibitors					X	X	X			X	
Barbiturates					X		X				
Lithium					X						
Cardiac glycosides					X	X					
Theophyllines					X						
Calcium channel blockers					X		X				
Stimulants			X			X					
Narcotic agents			X								
Amiodarone					X						
Macrolides					X						
2nd gen. Antihistamines					X						
MAO Inhibitors					X						

ID Insufficient dose
IDU Incorrect duration
OU Overutilization
UU Underutilization
DDI Drug/drug interaction
DDC Drug/disease contraindication
TD Therapeutic duplication
HD High dose
O^1 Concurrent use of TCA and SSRI, two or more prescribers
O^2 During pregnancy
O^3

Medicaid Recipient Lock-in Program

The purpose of the Recipient Lock-in Program (RLP) is to coordinate the provision of health care services for recipients who abuse or misuse Medicaid benefits by seeking duplicate or medically unnecessary services. Coordination of recipient health care services is intended to improve the quality of care for the recipient and reduce unnecessary physician and pharmacy utilization, while ensuring reasonable access to necessary Medicaid services.

Referrals of recipients as candidates for lock-in are received from the state, the drug utilization review program, physicians, pharmacists, other types of providers, and through automated surveillance methods. Once a referral is received, 6 months of pharmacy claims and diagnoses data are extracted from the Wisconsin Medicaid data warehouse, printed, and reviewed by a pharmacist. The pharmacist then recommends that one of the following actions be taken: enrollment in RLP, send alert letters to physicians, send warning letters to recipient, or no further action.

Those recipients receiving the recommendation for enrollment are sent a letter of intent, which explains their responsibility to not misutilize Medicaid services, the restriction that will be applied, how to designate a physician and pharmacy, and how to request a hearing if they wish to contest the decision for enrollment. If recipients fail to designate providers, the RLP may assign providers based on claims history. Administrative hearings are conducted by the Division of Hearings and Appeals and a pharmacist participates by telephone conference call. Recipients are also informed that access to emergency care is not restricted.

Upon enrollment, a second letter of notification is sent to the recipient and an initial letter of notification is sent to the lock-in physician and pharmacy. The second recipient notification letter informs them of their designated/assigned providers and effective dates of enrollment; explains their responsibilities while enrolled; and repeats how to request a hearing if they wish to contest the decision for enrollment. The notification letter to providers informs them of their designation/assignment as the lock-in provider of the recipient and explains their responsibilities as the lock-in provider.

Warning letters are typically sent to recipients who have some evidence of abuse or misuse of controlled substances but have not received any type of intervention from previous reviews. Alert letters are typically sent to physicians for recipients who received a warning letter but continued to have evidence of abuse or misuse of controlled substances.

A cost benefit analysis for interventions conducted in calendar year 2004 demonstrated that the RLP saves $3.13 per dollar spent. This analysis also demonstrated a 19% decrease in hospitalizations and 18% decrease in emergency room visits for the recipients included in the analysis.

Wisconsin Medicaid Recipient Lock-in Program Summary And Cost Benefit Analysis for CY04

RLP Summary - Calendar Year 2004	
	Number of Recipients
Profiles Reviewed	1288
Results of Profile Reviews	
Lock-in Recommendations	183
Recipient Appeals = 27	
Recipients for whom a Physician Alert Letters Sent	243
Warning Letters	163
Other (i.e., forward referrals to HMOs)	62
No further action	546
Release from RLP	67
Re-review in 6 months	47

Total for All Interventions: 260 Evaluable Recipients				
	6 Months Pre	**6 Months Post**	**Difference**	**% Savings**
ALL OTHER	$35,842	$45,551	$(9,708)	-27.1%
CAPITATION	$0	$0	-	
DENTAL	$20,956	$12,488	$8,468	40.4%
DME/DMS	$50,382	$24,916	$25,466	50.5%
DRUGS	$1,424,737	$1,320,555	$104,182	7.3%
EMERGENCY ROOM	$150,981	$103,855	$47,126	31.2%
HOME CARE	$16,477	$34,515	$(18,038)	-109.5%
INPATIENT HOSPITAL	$901,832	$767,905	$133,927	14.9%
LAB AND RADIOLOGY	$82,213	$66,365	$15,848	19.3%
MENTAL HEALTH	$31,656	$34,551	$(2,895)	-9.1%
NURSING HOME	$5,656	$26,886	$(21,230)	-375.3%
OUTPATIENT HOSPITAL	$139,018	$112,274	$26,744	19.2%
PHYSICIAN AND PHYSICIAN CLINIC	$307,977	$211,474	$96,503	31.3%
THERAPY	$2,076	$3,884	$(1,808)	-87.1%
TRANSPORTATION	$79,533	$68,135	$11,398	14.3%
Sum:	$3,249,335	$2,833,351	$415,983	12.8%
		Monthly Savings	$69,331	
	Monthly Savings per Recipient:		$267	
Monthly Cost Savings	$69,331	$3.13	= ROI	
Monthly Cost to Administer RLP	$22,180			
Utilization	**6 Months Pre**	**6 Months Post**	**Difference**	**% Decrease**
Count Hospitalizations	175	142	33	18.9%
Count ER Visits	824	672	152	18.4%
Count Prescriptions	15628	13829	1799	11.5%

Behavioral Pharmacy Feedback Project (BPFP)

The Division of Health Care Financing (DHCF) and the Wisconsin Bureau of Mental Health and Substance Abuse (BMHSA) implemented a new quality improvement program in May 2005. The Wisconsin Behavioral Pharmacy Feedback Program (BPFP) is designed to improve clinical care, while also holding down the projected increase in pharmacy costs. BPFP has partnered with Comprehensive NeuroScience, Inc. (CNS) to use available pharmacy claims data from Medicaid fee-for-service patients to compare the prescribing patterns of individual prescribers with national guidelines.

An advisory panel of Wisconsin psychiatrists, pharmacists, consumers, nurses and other stakeholders provides input on the specific intervention indicators that are used for this project. Prescribers who significantly depart from these indicators have received feedback comparing their own practice patterns with those of their colleagues.

Intervention Indicators

After a review of the available data and a discussion of mental health professionals' and patients' needs, the Stakeholder Advisory Committee approved intervention indicators in the following areas:

- Patients who are receiving 3 or more antipsychotic medications for more than 60 days (to allow crossover time).
- Patients between 18 and 64 who are receiving two different antipsychotic medications for more than 60 days, both at doses above FDA limits or both below FDA limits.
- Adults over 18 prescribed 5 or more drugs usually prescribed for mental illness for more than 90 days.
- Children under 18 prescribed 3 or more drugs usually prescribed for mental illness, for more than 60 days.

Project Goals

The experience from other states is that feedback to prescribers can improve the quality of care they provide, while potentially saving money for the Medicaid system. BPFP does not dictate to prescribers what they can or cannot prescribe. All change on the part of prescribers is voluntary. The individual prescriber will continue to be in the position of deciding whether a particular patient's needs justify the decision to deviate from typical prescribing practice.

The hope is that the information provided to prescribers will be useful, without being coercive. Experience from other states demonstrates that physicians will self-regulate their own prescribing patterns once they are fully aware of best-practice standards.